

REMARKS

Claims 1-9 are pending in the subject application and are subject to a restriction requirement.

Requirement for restriction under 35 U.S.C. 121

In the August 22, 2003 Office Action, the Examiner required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Groups 1-57. Claims 1-3 are drawn to a composition comprising at least two immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 530, subclass 300+. Applicant is required to elect a specific combination for examination. It was further noted that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Groups 58-114. Claims 4-8 are drawn to a host cell/composition comprising a host cell that comprises at least two immunogenic ligands selected from the group consisting of 6 immunogenic ligands, , insofar as the claims are drawn to a host cell comprising at least two immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 424 subclass 93.21. Applicant is required to elect a specific combination for examination. It was further noted that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Groups 115-171. Claim 9 is drawn to a method of inducing an immune response comprising delivering a peptide composition comprising two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 514 subclass 2+. Applicant is required to elect a specific combination for

examination. It was further noted that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Groups 172-228. Claim 9 is drawn to a method of inducing an immune response comprising delivering a composition comprising a host cell which comprises two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 424 subclass 93.21. Applicant is required to elect a specific combination for examination. It was further noted that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Request for reconsideration of restriction requirement under 37 C.F.R. 1.143

Applicants respectfully request a reconsideration and modification of this restriction requirement. The presently claimed inventions are drawn to compositions selected from 6 specifically defined peptide sequences, host cells comprising compositions selected from 6 specifically defined peptide sequences, and methods utilizing compositions selected from 6 specifically defined peptide sequences. By setting forth 228 groups from these claims, the instant restriction is unreasonable and inconsistent.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit. Pertinent to this policy,

Applicants point out that the instant restriction is inconsistent with previously issued restriction requirements for subject applications containing similar types of claim sets¹.

As stated by the Office, there are two criteria for a proper requirement for restriction between patentably distinct inventions, MPEP 803. First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner if restriction is required. The Examiner must examine the subject application on the merits even if it includes claims to distinct inventions if such an examination can be made without serious burden. Applicants assert that the search of claims 1-9 does not comprise such a serious burden that restriction into 228 inventions is proper.

Independent claims 1, 4, and 9 each contain a Markush grouping comprising 6 specifically defined peptide sequences. According to MPEP § 803.02, the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden.

"If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." MPEP § 803.02.

Applicants assert that these independent claims 1, 4, and 9 can be searched without serious burden.

First, the Office is capable of readily performing sequence searches of peptide sequences. The peptide sequences present in the instant claims are relatively uncomplicated. They uniformly consist of only 9 amino acids. Many sequences share related characteristics such as shared anchor residues, e.g. SEQ ID NOS 3, 5, 7 and 9. Additionally, Applicants have provided sequence listings for the instant sequences.

¹ The restriction requirement issued in application no. 09,862,260 on 16 July 2002 (enclosed in this communication as Appendix I) found 3 allegedly distinct inventions as contrasted with the 228 alleged by the instant restriction requirement. The restriction requirement issued in application no. 09, 922,405 on 8 September 2003 (enclosed in this communication as Appendix II) found 8,166 allegedly distinct inventions as contrasted with the 228 alleged by the instant restriction requirement. This inconsistency is notable due to the similarity in the claim sets under prosecution in each application.

These factors indicate that an examination of the peptide sequences contained in the Markush group of the instant claims can be reasonably performed.

Second, Applicants note that chemical cases with Markush groups, which often contain complicated chemical R group structures, are routinely searched without restriction. The instant claims do not contain complicated R groups. Rather, a search of the instant peptide sequences constitutes straight sequence searching. The different standard that the Office appears to be applying for Markush groups containing peptide structures is unsupported.

Third, the Office operates a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes, MPEP § 803.04. This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limits on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the 9-mer instant peptides) are considered reasonable to search. The Office also provides guidelines for the search of combinations of 10 or more individual sequences where they are claimed. In this case, the Office allows Applicants to elect a combination of ten or more sequences, which in the instant case would be only 6. As stated in MPEP § 803.04:

"If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth... More specifically, the combination will be searched until one nucleotide is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

Therefore, it appears that the Office readily recognizes that a search of a combination of 10 or more sequences does constitute a reasonable search and examination burden. Applicants point to the pertinent policy behind this decision in § 803.04:

"Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of

C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

Applicants assert that it is reasonable to apply a similar policy to the search of inventions containing peptide sequences, whose searches are performed similarly. This is more reasonable than the current restriction requirement under which suggests that 6 peptide sequences somehow comprise 228 individual inventions.

The application of the above-referenced nucleotide policy can be taken to a logical conclusion with respect to the instant peptide sequences. One could suppose that the Examiner did search the 6 claimed peptide sequences, as suggested is reasonable by the standard of the nucleotide policy. One could also suppose that all 6 sequences were novel and non-obvious. If so, one could logically conclude that all combinations comprising these 6 sequences are also novel and non-obvious. Using this logic, it is difficult to envision the benefit gained by examining the individual combinations as individual inventions as suggested by the instant restriction requirement. It appears rather that the Office has already considered this possibility with respect to nucleotide sequences and has set forth a reasonable policy.

Finally, Applicants suggest that the restriction requirement be modified to include three groups related to each of 1) the compositions of claim 1 and those dependent therefrom, 2) the host cell of claim 4 and those dependent therefrom, and 3) the method of claim 9.

If this requirement is not modified and is made final by the Examiner, Applicants further reserve the right to petition from requirement for restriction under 37 C.F.R. §1.144.

Provisional election with traverse required under 37 C.F.R. §1.143

In compliance with 37 C.F.R. §1.143, Applicants elect with traverse Group I with a specific composition comprising SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 13.

CONCLUSION

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date



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